UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,871	09/19/2000	Francois Mach	EGYP 3.0-009	5326

7590 07/15/2003

IVOR R. ELRIFI, ESQ.
MINTZ LEVIN
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	21

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/664,871	MACH, FRANCOIS	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,15-20 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,15-20 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *21-23* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2003 has been entered.

The cancellation of claims 4, 10-11, 38, and 39 in amendments filed April 30, 2003 is acknowledged.

Claims 1-3, 5-6, 15-20, and 35-37 are pending.

The outstanding obviousness type double patenting rejections of claims 1-3, 5-6, and 15-20 are withdrawn in view of the amendments made in the instant application as well as the different conflicting patent applications (See IDS in Paper No. 21 received April 30, 2003).

The outstanding statutory double patenting rejections are withdrawn in view of the amendments made in the instant application as well as the different conflicting patent applications (See IDS in Paper No. 21 received April 30, 2003).

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed April 30, 2003.

The outstanding rejection under 35 USC 102(e) is withdrawn in view of the amendments filed April 30, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent No. 10/056,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of Type I diabetes. The instant application recites a method of treating autoimmune diseases including Type I diabetes. The only difference is that the claims in the co-pending application recite specifically the method of treating Type I diabetes. One of ordinary skill in the art would have been reasonably expected to employ method of the instant application to treat Type I diabetes because the instant method is useful to treat various autoimmune disorders including Type I diabetes. Therefore, one of ordinary skill in the art would be motivated to employ the instant method to specifically treat Type I diabetes since similar therapeutic effects would have been reasonably expected.,

Claims 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent No. 10/056,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of inflammatory conditions including rheumatoid arthritis. The instant application recites a method of treating autoimmune diseases including rheumatoid arthritis. The only difference is that the claims in the co-pending application recite specifically the method of treating rheumatoid arthritis. One of ordinary skill in the art would have been reasonably expected to employ method of the instant application to treat rheumatoid arthritis because the instant method is useful to treat various autoimmune disorders including rheumatoid arthritis. Therefore, one of ordinary skill in the art would be motivated to employ the instant method to specifically treat rheumatoid arthritis since similar therapeutic effects would have been reasonably expected.

Claims 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent No. 10/056,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of autoimmune disorders including multiple sclerosis. The instant application recites a method of treating autoimmune diseases including multiple sclerosis. The only difference is that the claims in the co-pending application recite specifically the method of treating multiple sclerosis. One of ordinary skill in the art would have been reasonably expected to employ method of the instant application to

treat multiple sclerosis because the instant method is useful to treat various autoimmune disorders including multiple sclerosis. Therefore, one of ordinary skill in the art would be motivated to employ the instant method to specifically treat various autoimmune disorders including multiple sclerosis since similar therapeutic effects would have been reasonably expected.

Claims 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent No. 10/056,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of autoimmune disorders including psoriasis. The instant application recites a method of treating autoimmune diseases including psoriasis. The only difference is that the claims in the co-pending application recite specifically the method of treating psoriasis. One of ordinary skill in the art would have been reasonably expected to employ method of the instant application to treat psoriasis because the instant method is useful to treat various autoimmune disorders including psoriasis. Therefore, one of ordinary skill in the art would be motivated to employ the instant method to specifically treat various autoimmune disorders including psoriasis since similar therapeutic effects would have been reasonably expected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35–37 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Claim 35 is very broad. The expression "a compound that inhibits HMG-CoA reductase" merely indicates what the compound is capable of doing, instead of disclosing what the compound is. Such terms encompassed any natural or non-natural compounds and functionally equivalent thereof (See page 9 in the instant specification).

Applicant fails to set forth the criteria that define "a compound that inhibits HMG-CoA reductase" (e.g., how much inhibition of HMG-CoA reductase would make the compound suitable for the invention?). Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a few compounds are disclosed as working examples. Please note that these examples are neither exhaustive nor indicate the class of compounds required. Pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "a compound that inhibits HMG-CoA reductase", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation. Furthermore, the instant claim recites functional language in attempts to point out what compounds would be appropriate in practicing the instant invention. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the

invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Claim 36 is very broad. The expression "compound that has therapeutically insignificant lipid-lowering effect" encompasses any compound that has therapeutically insignificant lipid-lowering effect. However, Applicant fails to set forth the criteria that define a "compound that has therapeutically insignificant lipid-lowering effect". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, no example of "compound that has therapeutically insignificant lipid-lowering effect" is set forth, thereby failing to provide sufficient working examples. It is not known what class of compounds would be required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "compound that has therapeutically insignificant lipid-lowering effect",

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim 37 is very broad. The expression "a compound, capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression" merely indicates what the compound is capable of doing, instead of disclosing what the compound is. Applicant fails to set forth the criteria that define "a compound, capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a few compounds are disclosed as working examples. Please note that these examples are neither exhaustive nor indicate the class of compounds required. pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "compound(s), capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation. Furthermore, the instant claim recites functional language in attempts to point out what compounds would be appropriate in practicing the instant invention. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to

functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-6, 15-20, and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, and 3 recite the limitation "said mammal" in line 6. There is insufficient antecedent basis for this limitation in the claim.

The expression "therapeutically insignificant lipid-lowering effect" in claim 36 is a relative term which renders the claim indefinite. The expression "therapeutically insignificant lipid-lowering effect " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant specification, page 18, applicant attempts to define what "therapeutically significant" is with regard to the sterol synthesis. However, it is still not clear what this expression encompass. In other words, how low the lipid-lowering effect would be considered as "therapeutically insignificant"? Furthermore, because such expression is indefinite, it is also unclear as to the compound that has a "therapeutically insignificant lipid-lowering effect" encompassed by the claim.

The expression "a compound, capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression" in claim 37 render the claim indefinite as to the compound encompassed by the claim. It is not clear what compound would be considered as "capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression". Therefore, the metes and bounds of the claim are not defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 15-16, 18-20, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hommel et al. (Diabetologia, 1992; 35(5):447-451).

Hommel et al. teaches a method of administration of simvastatin, in a dose of 10 or 12.5mg daily, to Type I diabetic patients (See the abstract, also, page 448, col. 2, last three paragraphs).

Claims 1-3, 6, 15-20, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Driscoll et al. (Circulation, 1997; 95:1126-1131).

Driscoll et al. teaches a method of simvastatin, in a dose of 20mg daily, to artherosclerotic patients (See the abstract).

Claims 1-3, 5-6, 15, 20, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al. (EP 0 482 498).

Pan et al. teaches the employment of HMG CoA reductase inhibitors such as lovastatin or pravastatin in treating Type I or Type II diabetic patients for reducing the risk of developing diabetic complications (See page 2, line 13-14; and claim 3).

The instant claims are drawn to a method of achieving MHC-class II mediated immunomodulation, immunosuppression, or anti-inflammatory effect in human by administering a HMG-CoA reductase inhibitor, such as simvastatin, to patients suffered from psoriasis, Type I diabetes, multiple sclerosis, rheumatoid arthritis, and artherosclerosis. The only method step is administering the effective amount of HMG-CoA reductase inhibitors to a patient suffered from the herein recited disorders.

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such treatment use. Arguments that such treatment use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the

instant application, Applicants' failure to distance the proffered claims from the anticipated treatment utility, renders such claims anticipated by the prior inherent use.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5-6, 15-20, and 35-37 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

7/10/03

San-ming Hui
Patent examiner
Art Unit 1617
July 10, 2003